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TITLE: Quality of Life and Cost Effectiveness of Prostate Cancer Treatment

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| 14. ABSTRACT Study objective is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of cost effectiveness and HRQoL for men with prostate cancer from two health care systems: Veterans Affairs (VA) and non-VA (UPHS). Specific aims: Controlling for stage at diagnosis and co-morbidity, (1) analyze progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze resource utilization patterns, treatment modalities and quality of life of men with prostate cancer between non-VA and VA hospitals. For this prospective cohort study, we have completed the required recruitment and have established a successful recruitment and retention program. In total, we have recruited 310 patients (<65) from the Urology and Radiation Oncology clinics, UPHS and VA medical center with a retention rate of more than 85% for our follow-up surveys. Using the study results, we have published four articles, one manuscript is under review and presented eight peer-reviewed abstracts (three in this reporting period) in national and international conferences. In continuation of our June 2007 report, in this report we have presented the cost-effectiveness. | | | | | |
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INTRODUCTION

Proposed Abstract:

Background: Cost and health-related quality of care are particularly relevant to prostate cancer because of multiple treatment options with varying outcomes. Due to uncertainty in the screening and treatment, debate on outcomes such as quality of life, satisfaction with care and cost of care continues. Our recent research indicated that type of treatment received for a given stage of prostate cancer varied by ethnicity and age. Men with early stage prostate cancer often live long after diagnosis and treatment and desire to maximize their quality of life. The outcome of this study will facilitate clinical and policy decision making for effective and equitable care.

Objectives/Hypothesis: The objective of this study is to assess the effects of differential treatments for prostate cancer on quality of life and cost of care for two ethnic groups. It will also include comparison of efficiency and HRQoL for men with prostate cancer from two health care systems: Veterans Affairs (VA-public) and non-VA (UPHS-private).

Specific Aims: controlling for stage at diagnosis and comorbidity, (1) analyze and compare progression of cancer, HRQoL, incremental cost and satisfaction with care of prostate cancer patients across two ethnic groups, (2) analyze and compare short and long term cost-effectiveness of prostate cancer treatment across ethnic groups; and (3) analyze and compare resource utilization patterns, treatment modalities and quality of life of men with prostate cancer between non-VA and VA hospitals.

Study Design: This study uses a prospective cohort design to assess and compare across Caucasians and African Americans, health related quality of life (HRQoL) and cost of care for prostate cancer patients, younger than 65 years of age. A total of 300 participants will be recruited from the urology services at the Hospital of the University of Pennsylvania (HUP) and Philadelphia VA Medical Center. Data will be collected on patient age, ethnicity, education, date of prostate cancer diagnosis and treatment, health insurance, diagnostic and therapeutic procedures, inpatient hospitalizations, PSA, PSADT, Gleason score, cancer stage (TNM), physician and ambulatory clinic visits, laboratory and x-ray, and pharmaceuticals. To assess HRQoL, all participants will receive the Prostate Cancer Index, SF-36, family out of pocket-indirect cost survey and CSQ-8 via mail and a follow up phone call. Baseline data will be collected within 1-2 weeks after diagnosis of prostate cancer. Subsequent follow up will be done at three months' interval up to two years. We will compare mean direct medical and incremental cost of care for all conditions and HRQoL across two ethnic groups, controlling for stage and Charlson comorbidity score. HUP costs for the same services will be applied to VA patients. Cost-effectiveness of prostate cancer treatment will be compared across ethnic groups. We will obtain data on primary sources of treatment and costs from hospital medical records, chart review, and hospital based administrative database (Pennsylvania Integrated Clinical and Research Database system). Descriptive and inferential statistical (t-test, chi-square, and odds ratio) analysis will be performed. PSA doubling time will be computed and compared across ethnic groups. Logistic and pooled regression models will be used. The dependent variables of two separate regression models are total cost and quality of life. The independent variables are age, treatment type, health insurance, Charlson co-morbidity score, PSA level and Gleason score. The regressions will be repeated for both ethnic groups and parameters of estimates will be compared. Stratified analysis will be performed based on ethnicity, stage at diagnosis and treatment type. Factors associated with progression of cancer will be analyzed and compared across groups. Finally, Markov models will be used to analyze and compare cost-effectiveness and progression of prostate cancer treatments across two ethnic groups and comparison will be made between VA (public) and non-VA (private) hospitals.

BODY

After completing the final research protocol, the process of recruiting newly diagnosed prostate cancer patients for this grant was initiated in February of 2004. Per objective of this Health Disparity Scholar Award study, we have completed the recruitment of 310 younger (< 65 years) newly diagnosed prostate cancer patients. Also, combining our prior New Investigator Award, we have recruited a total of 597(< 65 yrs=310 = 65 yrs=287) men with prostate cancer as of January 2007. The specific steps of this process are: (1) contacting the patients; (2) explaining the study; and (3) obtaining the consent. Detailed discussion and analysis of preliminary results are presented as follows. All the tasks, activities, analyses and results reported here are pertaining to the Health Disparity Scholar Award.

Task 1. Recruitment of Patients- Completed (Please refer to June 2007 report)

Task 2: Baseline Data Collection- Completed (Please refer to June 2007 report)

Task 3: Administration of Patient Satisfaction Questionnaire - Completed (Please refer to June 2007 report)

Task 4: Develop Plan for Follow-up Patient interview-Completed (Please refer to June 2007 report)

Task 5: Follow up interview and Health Related Quality of Life, and Direct medical care cost, health resource utilization- Data Collection – Completed (Please refer to June 2007 report)

Task 6: Indirect Cost Data Abstraction Design – Completed (Please refer to June 2007 report)

Task 7: Abstraction of Medical Records - Completed (Please refer to June 2007 report)

Task 8: Annual Report, Months 11-12-Completed (Please refer to June 2007 report)

Task 9: Data entry and coding – Completed (Please refer to June 2007 report)

Task 10: Interim Analysis, Months 22-24 – Completed (Please refer to June 2007 report)

Task 11: Cost-Effectiveness Model, Month 30-3 – completed and reported in this progress report

Task 12: Interim Analyses and final analysis- completed (Please refer to June 2007 report)

a. Interim statistical analyses was performed at the second year of the study.

The final analyses are currently ongoing and will be submitted during final report.

Task 13: Publishable reports will be developed – completed

This task is currently ongoing. We have published four articles in the Journal of Urologic Oncology, Journal of Urology, British Journal of Urology and CANCER journal. One manuscript is currently under review (Appendix). We have also presented eight peer reviewed abstracts (three in this grant period) at the various national and international conferences. Additionally, seven more manuscripts are in progress. Please note that the publication outcomes are results of this health disparity scholar award and previous new investigator award from the DOD. We sincerely apologize for an oversight in prior publications in acknowledging this award.

Task 11: Cost-Effectiveness Model, Moth 30-36 - completed

Cost Effectiveness (CE) of Treatment: CE analysis is a useful measure of quantifying the tradeoff between resources consumed and health outcomes achieved with the use of specific treatment. The technique can help physicians, health plans, insurers, government agencies, and individuals to prioritize services and to allocate health care resources. Typical measures of health outcomes are either years of life saved or quality-adjusted life years (QALYs) saved. A cost-effectiveness model that attempts to include these cost and benefits is the cost for QALY. The data collected on resource use and QALY was used to compute cost effectiveness ratio between treatment groups. The net cost per utility ratio was defined as the net cost (cost of treatment group1 - cost of treatment group2, divided by net QALYs (QALY treatment 1 - QALY treatment 2). Incremental cost-effectiveness was used to analyze and compare the effectiveness of different treatments.

METHODOLOGY

Our prospective study sample consists of 310 newly diagnosed prostate cancer patients receiving treatment at the University of Pennsylvania Health System (Hospital of the University of Pennsylvania, Pennsylvania hospital, and Presbyterian Medical Center) and Philadelphia VA Medical Center (PVAMC). Please refer to the June 2007 report for detailed description of recruitment and retention process.

Inclusion and Exclusion criteria for CE Analysis

Inclusion Criteria:

- (1) Patients must be treated for prostate cancer at the Hospital of the University of Pennsylvania (HUP), Pennsylvania hospital, Philadelphia VA, or Presbyterian Medical Center.
- (2) Age: ≥ 45 years
- (3) Race: Self-identified as African American or Caucasian.
- (4) Newly diagnosed prostate cancer
- (5) Localized prostate cancer
- (6) Gleason score > 4 and < 8 .
- (7) Primary treatment: Radical prostatectomy or external beam radiation therapy
- (8) Written informed consent provided

Exclusion Criteria:

- (1) Age: ≥ 65 years
- (2) Distant, metastatic or un-staged prostate cancer at the time of diagnosis.
- (3) Gleason score of 2-4 and > 8 at the time of diagnosis
- (4) PSA > 20 ng/mL at the time of diagnosis
- (5) Patients who visited the clinics to obtain second opinion and not to receive treatment
- (6) Patients who moved to another location or facility and
- (7) Inability to communicate in English.

OUTCOME ASSESSMENT

Quality of Well-Being: The Quality of Well-Being (QWB-SA) is a performance-oriented, preference-weighted measure. It combines symptoms and problems (CPX) with three scales of functioning-mobility (MOB), physical activity (PAC), and social activity to produce a point-in-time expression of well-being that runs from 0

(for death) to 1.0 (for asymptomatic full function). This self-administered survey has showed acceptable performance for wide variety of medical and surgical conditions. QWB uses rating scale compared to other utility measures that use time trade-offs and/or standard gambles to obtain preference data. The advantage of standard gamble and time tradeoff methods is their clear link to economic theory. Their drawback however, is that many of the assumptions underlying economic measurements of choice can be challenged. Human information processors do poorly at integrating complex probability information while making risky decisions. Often the gambles used in the standard gamble tasks are dissimilar to decisions required of real patients. Also, cognitive demands of the tasks are high. The time trade off is theoretically appealing since it is conceptually equivalent to quality adjusted life years (QALY). However, studies have questioned if the tasks can be understood clearly by an average subject. Determining preference using standard gamble and time tradeoff may lead to uncertainty in the validity of answers. The rating scale such as QWB is generally the easiest technique to understand. QALYs integrate mortality and morbidity to express health status as equivalent of well years of life. The QWB is associated with a General Health Policy Model that combines group QWB mean scores with group numbers to allow calculation of differences in well-years experienced by groups at a point-in-time, as well as over time. The QWB has been validated for various illnesses and exhibits excellent reliability and sensitiveness.

Quality of Life Adjusted Life Year (QALY): Quality-adjusted life-year is defined as the equivalent of completely well year life, or a year of life free of any symptoms, problems, or health-related disabilities. Using the scores obtained by the Quality of Well-being-SA and applying General Health Policy Model we computed the QWB scores. The model for point-in-time Quality of Well-Being is

$$\begin{aligned} \text{Quality of well-being scale (QWB)} = & 1 + (- \text{observed mobility} \times \text{mobility weight}) \\ & + (- \text{observed physical activity} \times \text{physical activity weight}) \\ & + (- \text{observed social activity} \times \text{social activity weight}) \\ & + (- \text{observed symptoms/problem} \times \text{symptom/problem weight}). \end{aligned}$$

Thus, $\text{QALY} = \text{QWB} \times (\text{duration in years})$.

Measurement of Cost of Care:

Direct costs include costs of care provided by physicians and other health care professionals, care provided in hospitals and other institutions, medications, laboratory services and research. We used following data to measure direct costs of prostate cancer illness: hospital care costs, physician and care givers payments, medication costs, costs related to detection, costs associated with initial and follow-up treatments, and treatment of complications. The primary source of cost data for all University of Pennsylvania Health System (UPHS) patients was the Pennsylvania Integrated Clinical and Research Database (PICARD). For the Philadelphia VA patients, the data on type and number of services received patients, including those attributable to prostate cancer, was obtained from patient treatment file, outpatient care file, and medical chart review. VA cost data was computed using average cost per DRG weight (10). The Cost Distribution Report of the VA was matched to patient treatment file and outpatient care file to compute average cost per visit. Two cost estimates were done per patient for the duration of our study. First, total average costs of medical care (including prostate cancer) was computed and compared between groups. Next, the average cost of medical care attributable to prostate cancer treatment was computed and compared between groups by identifying the procedures, ICD-9 and DRGs attributable to prostate cancer. To determine the overall cost of medical care for the study period of two years, the cumulative cost for each patient per year was computed and adjusted to the 2007 dollars. Cost per service was attributed to each service for each patient from actual payments

ANALYSIS

The statistical analysis was conducted in three stages. In the first stage, we checked for data quality and carried out descriptive analyses of demographics and key baseline and outcome variables. In the second stage, we analyzed the effects of treatment, ethnicity and age on outcome variables (Please refer to previous report, June 2007). In the third stage, we used cost-effectiveness analysis to analyze treatment effect estimates.

Estimation of Effects of Treatment

Cost-effectiveness Analysis: The main thrust of these analyses is to estimate the effect of treatment on cost and effectiveness, as measured by QALY. These analyses are then combined into a single cost-effectiveness analysis. For the main analysis, each subject contributes a single value of total treatment cost and QALY. These analyses restrict the cost accrual and survival to the two-year follow-up period.

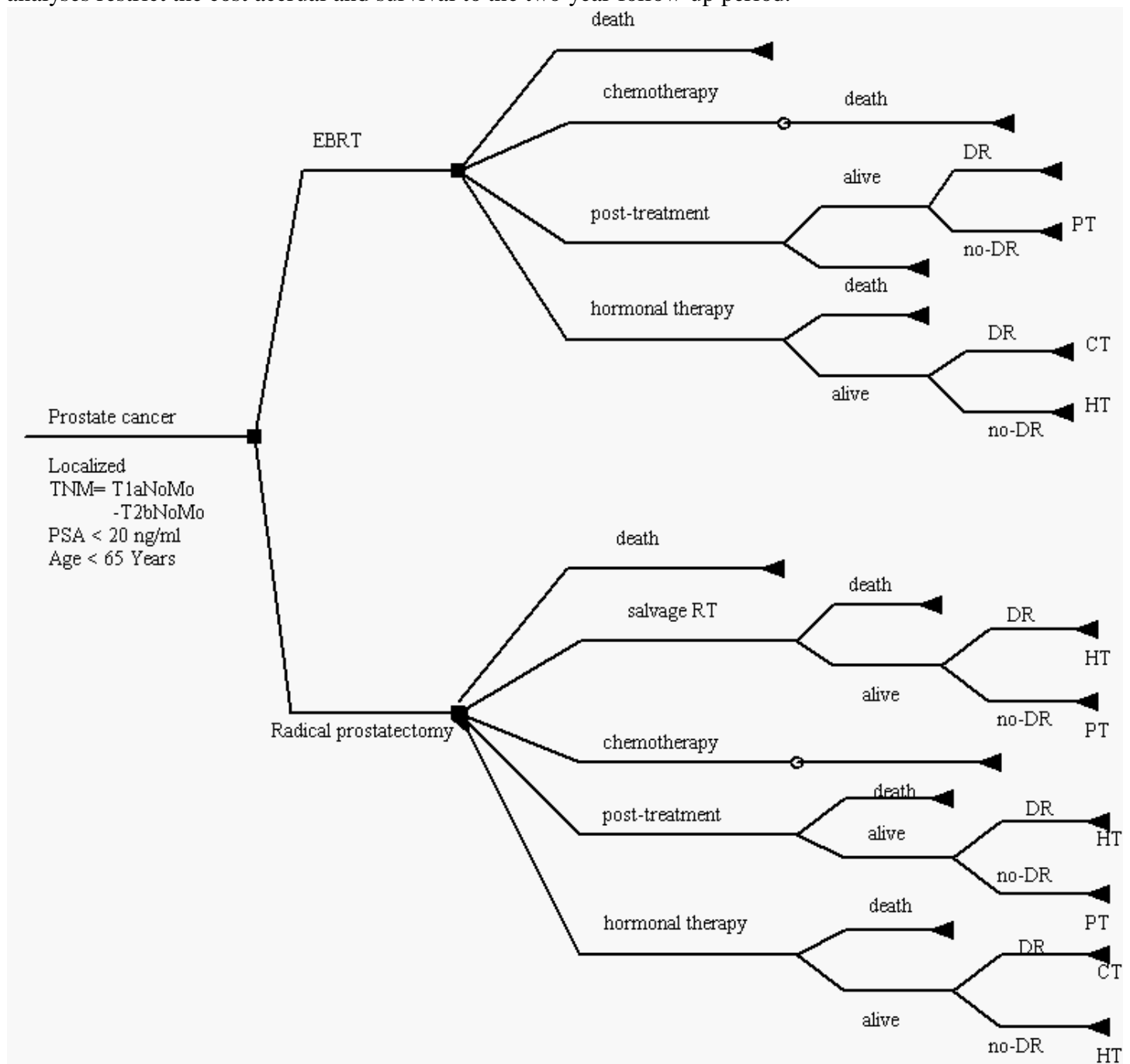


Figure 1: Prostate cancer Markov Model to analyze the effectiveness of radical prostatectomy and external beam radiation therapy
PT: Post treatment; CT: Chemotherapy; HT: Hormonal therapy; DR: Disease recurrence

Figure 1 presents the Markov model used with following health states: disease recurrence, post treatment, hormonal therapy, chemotherapy and death. Patients are considered to have spent six months in each state before opportunity to transition to another state or stay in the same state. Sensitivity and simulation analysis was used to analyze the project impact on overall cost and effectiveness of each treatment group population. . Transition probabilities (probability of moving from one health state to another) were derived from the study results. Cancer grade, patient age, and co-morbidities were considered with Monte Carlo sensitivity analysis. Cohorts (< 65 years) of radical prostatectomy or external beam radiation therapy as primary treatment were

followed for 20 years. We considered a discount rate of 5% and all costs were based on 2007 dollars. The range of parameters used for the sensitivity analysis is presented in Table 1.

Table 1: Sensitivity Analysis Values

| | Variables | Value | Range |
|---|---|--|------------------------------------|
| 1 | Age years | 57 | 50-65 |
| 2 | Cost of treatments: Radical prostatectomy External Beam radiation therapy | 15,494 20,615 | 10,000 - 30,000 15,000 - 40,000 |
| 3 | Utility Radical prostatectomy External Beam radiation therapy | 0.73 0.62 | 0.60-1.0 0.50-1.0 |
| 4 | Disease Recurrence Radical prostatectomy External Beam radiation therapy | 98% at five years 85% at five years | 80% - 100% 70% - 90% |
| 5 | Cost of hormonal therapy Utility of hormonal therapy | \$8,200 0.55 | \$8,000 - \$20,000 0.3 -0.95 |

RESULTS AND DISCUSSIONS:

As presented in Table 2, total mean cost of prostate cancer care and utility values vary significantly between VA and non-VA hospitals. Non-VA patients reported significantly higher utility values and higher costs during their first year of treatment. During the second year after treatment, the non-VA group continued to show higher utility compared to VA group. The second year costs were lower for the non-VA group compared to the VA group.

Table 2: Direct Medical Care cost (\$) and utility values (age< 65 yrs)

| | Year One | | | Year Two | | |
|-----------------|----------|--------|--------|----------|--------|--------|
| | All | Non-VA | PVAMC | All | Non-VA | PVAMC |
| Mean Inpatient | 21,921 | 21449 | 20,102 | 11,062 | 2018 | 10303 |
| Median | 30187 | 22685 | 22,600 | 0 | 0 | 0 |
| Mean Outpatient | 6,994 | 3873 | 1,434 | 5,062 | 1612 | 3468 |
| Median | 4,785 | 1523 | 0 + | 1,399 | 224 | 4270 + |
| Mean Emergency | 32 | 30 | 0 | 26 | 19 | 0 |
| Median | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean Total | 28,948 | 25352 | 21536* | 16,155 | 3648 | 13771* |
| Median Total | 36,325 | 24833 | 22600 | 1,663 | 228 | 4872 |
| Utility | 0.6859 | 0.7208 | 0.6311 | 0.7200 | .7501 | .6803 |

* Log t-test, significant at .05 level; + Wilcoxin test for median values significant at .005 level

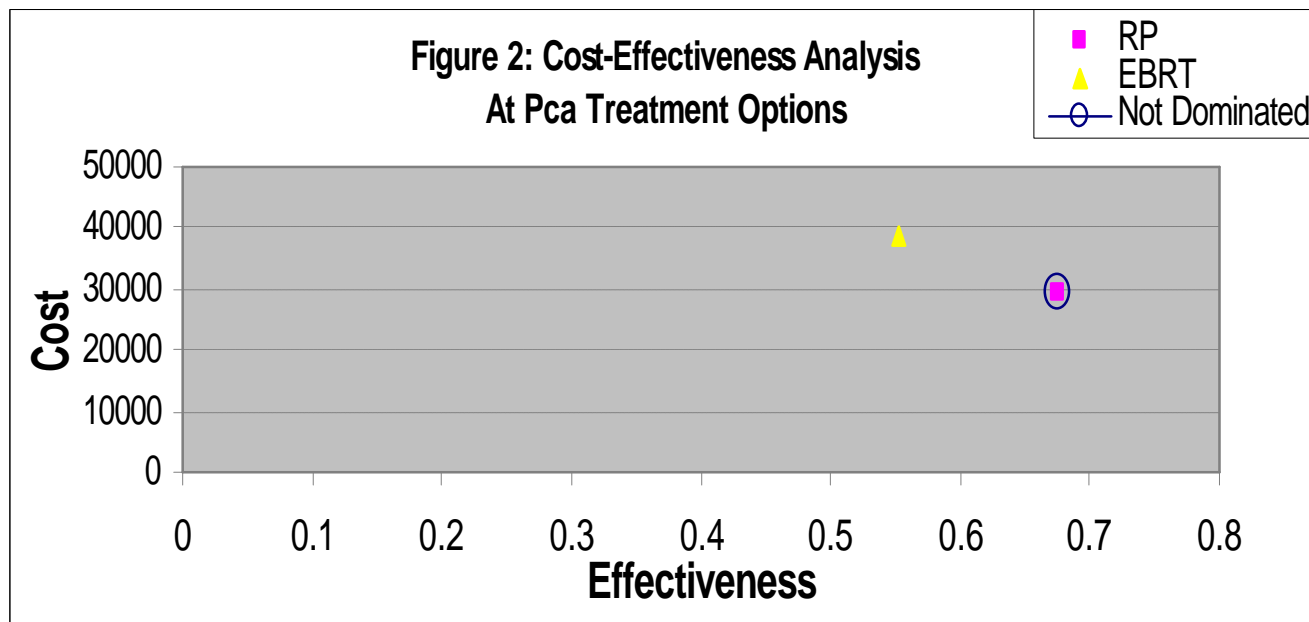
Table 3 presents cost and utility comparisons between two treatment groups. It is noted that costs were higher for the RP treatment during the first year, compared to the EBRT treatment. However, the costs of RP group were lower than the EBRT group in the second year. Also, the RP group continued to report higher utility than the EBRT group in both years.

Table 3: Direct Medical Care cost (\$) and utility (age< 65 yrs)

| | Year One | | | Year Two | | |
|-----------------|----------|-------|--------|----------|-------|--------|
| | All | RP | EBRT | All | RP | EBRT |
| Mean Inpatient | 21,921 | 22419 | 12784 | 11,062 | 1731 | 19891 |
| Median | 30187 | 22670 | 18375 | 0 | 0 | 0 |
| Mean Outpatient | 6,994 | 3049 | 4665 | 5,062 | 1674 | 3823 |
| Median | 4,785 | 1376 | 2406+ | 1,399 | 247 | 4270+ |
| Mean Emergency | 32 | 27 | 0 | 26 | 14 | 67 |
| Median | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean Total | 28,948 | 25494 | 17448* | 16,155 | 3417 | 23781* |
| Median Total | 36,325 | 24677 | 15592 | 1,663 | 249 | 4944 |
| Utility | .6923 | .7318 | .6196 | .8092 | .8328 | .7061 |

* Log t-test, significant at .05 level; + Wilcoxin test for median values significant at .005 level

Results of the cost-effectiveness are presented in Figure 2. It is noted that the RP treatment is dominating the EBRT treatment in terms of cost-effectiveness.



Cost-Effectiveness Analysis

| Strategy | Cost | Incr Cost | Eff | Incr Eff | C/E | Incr C/E (ICER) |
|----------|-------|-------------|-------------|----------------|----------------|-----------------|
| RP | \$29K | 0.676 QALYs | | 43,337 \$/QALY | | |
| EBRT | \$39K | \$10K | 0.553 QALYs | -0.123 QALYs | 70,136 \$/QALY | (dominate) |

Figure 3 presents the cost-effectiveness acceptability curve for a patient of age 57 years, comparing the two treatments-RP and EBRT. The probability of cost-effectiveness increases as the willingness to pay increases. Thus RP treatment is shown to have higher probability of cost-effectiveness, compared to EBRT.

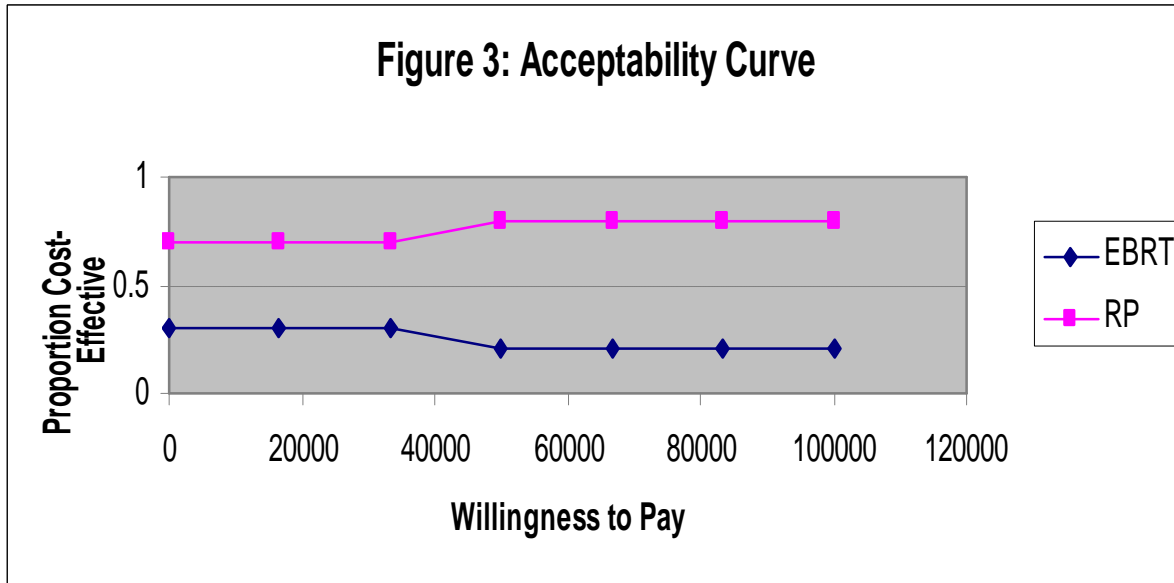
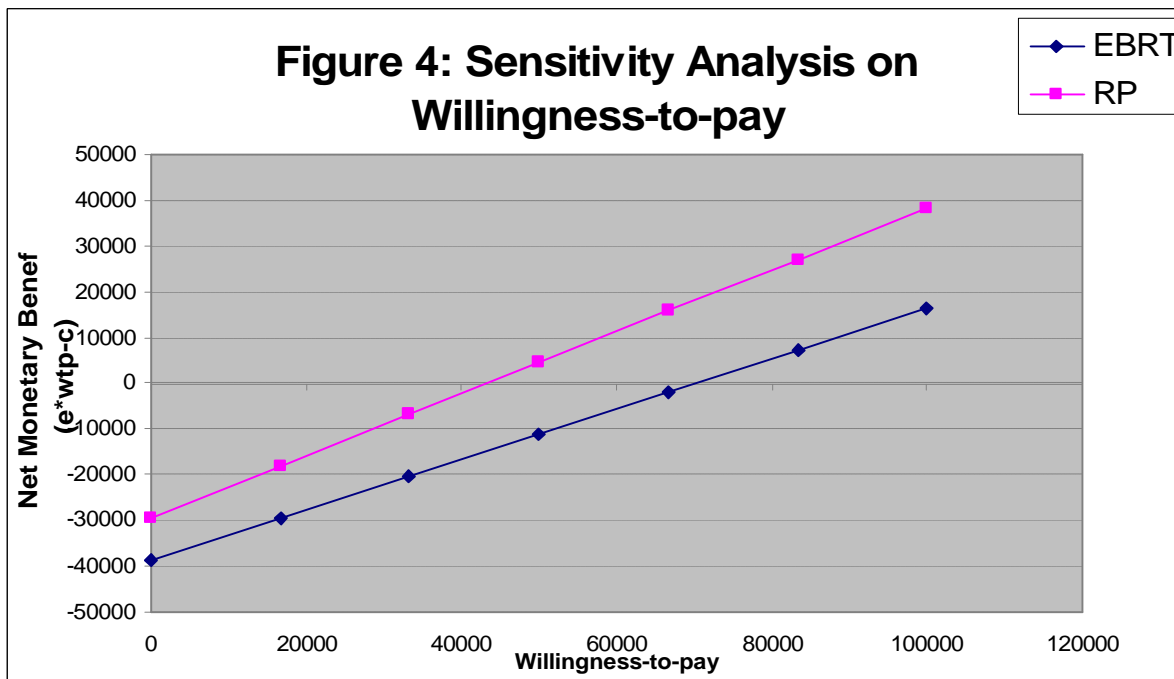


Fig 4 presents the Net Monetary Benefit curve for the two treatments –RP and EBRT. The treatment with the highest NMB would be the preferred treatment and thus it is noted that RP treatment is the preferred treatment, compared to EBRT.



KEY RESEARCH ACCOMPLISHMENTS

During the study period between 2/1/2007 to 1/31/2008, we have completed the recruitment of newly diagnosed prostate cancer patients and have established an effective recruitment and follow up mechanism. We have successfully completed recruited of total 310 (< 65 years) newly diagnosed prostate cancer patients from the urology clinic, radiation oncology clinic of the University of Pennsylvania and VA Medical Center. Final phase (24 month follow-up) of data collection on Health Related Quality of Life, Satisfaction with Care, Direct and Indirect medical cost at baseline and follow-up has been completed. During this report period, we have achieved an overall retention rate of more than 85%. We have completed the cost-effectiveness analysis and have developed a Markov model to evaluate the treatment modalities for prostate cancer care. We have completed all the tasks for this grant award. Using the results of the study, we have published four articles, one manuscript is currently under review (please see Appendix) and we have presented in six national and international conferences.

REPORTABLE OUTCOMES

Published Articles:

- (1) Jayadevappa R, Chhatre S, Weiner M, Bloom BS, S Malkowicz B. Medical Care Cost of Patients with Prostate Cancer. Urologic Oncology: Seminars and original Investigations, 23 (2005): 155-162.
- (2) Jayadevappa R, Bloom BS, Chhatre S, Fomberstein KM, Wein AJ, S Malkowicz B. Health Related Quality of Life and Direct Medical Care cost in newly diagnosed younger men with prostate cancer. The Journal of Urology, 2005, 174:1059-1064.
- (3) Jayadevappa R, Chhatre S, Whittington R, Bloom BS, Wein AJ, S Malkowicz B. Health Related Quality of Life and Satisfaction with Care among Older Men Treated with Radical Prostatectomy or External Beam Radiation Therapy. BJU International. 2006, 97: 955-962
- (4) Jayadevappa R, Chhatre S, Bloom BS, Wein AJ, S Malkowicz B. Ethnic Differences in Health Related Quality of Life and Satisfaction with Care among Older Men with Prostate Cancer. CANCER June 1, 2007, 109:2229-2238.
- (5) Jayadevappa R, Chhatre S, Schwartz JS, Wein AJ, S Malkowicz B. Satisfaction with Care – A Measure of Quality of Care among Prostate Cancer Patients? **-under review- (Appendix)**

I. Peer Reviewed Abstract:

1. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Hospital Ownership and Quality of Prostate Cancer Care. American Urological Association Annual Meeting, Anaheim, CA- May 2007.
2. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Assessment of Indirect Costs of Newly Diagnosed Prostate Cancer Patients. American Urological Association Annual Meeting, Anaheim CA, May 2007.
3. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Variation in Indirect Costs of Newly Diagnosed Prostate Cancer Patients. Innovative Minds in Prostate Cancer Tdoay-IMPACT, Sept 5-8, 2007, Atlanta GA.

Working Manuscripts: (under preparation)

1. Jayadevappa R, Chhatre S, Schwartz SJ, Wein AJ, S Malkowicz B. Assessment of Indirect cost of Care of Newly Diagnosed Prostate Cancer patients.
2. Jayadevappa R, Chhatre S, Schwartz SJ, Wein AJ, S Malkowicz B. Predictors of Quality of Wellbeing of Newly Diagnosed Prostate Cancer Patients.
3. Jayadevappa R, Malkowicz SB, Wein A, Chhatre S. Predictors of Health Related Quality of Life and Cost of Care of younger Prostate Cancer Patients.

4. Jayadevappa R, Chhatre S, Wein A, Whittington R, Malkowicz SB. Variations in Health Related Quality, satisfaction with care and direct medical care cost of newly Diagnosed Prostate Cancer Patients Across Ethnicity.
5. Jayadevappa R, Malkowicz SB, Whittington R, Wein A, Chhatre S. Treatment pattern and Health Related Quality of Life of VA and non-VA prostate cancer patients.
6. Jayadevappa R, Malkowicz SB, Schwartz SJ, Wein A, Chhatre S. Cost-Effectiveness of Prostate Cancer Treatment-A Prospective Study.
7. Jayadevappa R, Malkowicz SB, Whittington R, Wein A, Chhatre S. Minimally Important Difference of HRQoL of Newly Diagnosed Prostate cancer patients.

CONCLUSIONS

All the proposed targeted activities have been achieved during the study period. We have a well-established recruitment and retention mechanism in place. We have completed the patient recruitment and follow-up tasks. In total we have recruited 310 newly diagnosed prostate cancer patients (< 65 years) and our overall retention rate is currently higher than 85%. All the data has been entered, with established quality control measures. We have all analysis and all of the reported tasks. Final analysis and modeling is complete. In addition, we have been able to publish four articles and present six abstracts at the national and international conferences. One manuscript is currently under review (please see Appendix). The analyses have yielded the following conclusions:

- (1) African American men exhibited poorer post-treatment outcomes and may take longer time to return to their baseline HRQoL values, compared to Caucasian younger men. This information is important in planning for and communicating with patients about the post treatment period.
- (2) We observed significant variation in treatment pattern and outcomes between two ethnic groups. African American men presented with higher Charlson comorbidity score compared to Caucasian men.
- (3) Post treatment PSA levels were comparable across ethnicity and hospital type.
- (4) We observed significant variation in treatment pattern and outcomes between VA and non-VA prostate cancer patients.
- (5) External beam radiation therapy (EBRT), higher baseline PSA and VA hospital type are associated with lower HRQoL and lower satisfaction with care of PCa patients at 12 months post-treatment.
- (6) Type of treatment received appears to have significant association with post-treatment quality of well being. Thus, assessment of quality of wellbeing provides an important quantitative tool to support patient and physician clinical treatment decision making process in prostate cancer care.
- (7) Comparison of indirect cost of prostate cancer care between two ethnic groups and two hospital groups showed significant variation over time and groups.
- (8) We observed significant variation in direct medical care costs across hospitals and ethnic groups, after controlling for stage of cancer, age and Charlson co-morbidity.
- (9). Cost-effectiveness analysis indicated that compared to external beam radiation therapy (EBRT), radical prostatectomy (RP) was a cost-effective treatment for newly diagnosed younger prostate cancer patients.

APPENDIX

1. Publications:

- (1) Jayadevappa R, Chhatre S, Schwartz JS, Wein AJ, S Malkowicz B. Satisfaction with Care – A Measure of Quality of Care among Prostate Cancer Patients?

2. Peer Reviewed Abstracts (during this annual review period):

1. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Hospital Ownership and Quality of Prostate Cancer Care. American Urological Association Annual Meeting, Anaheim, CA- May 2007.
2. Jayadevappa R, Chhatre S, Whittington R, Wein AJ, S Malkowicz B (2007). Assessment of Indirect Costs of Newly Diagnosed Prostate Cancer Patients. American Urological Association Annual Meeting, Anaheim CA, May 2007.

Title Page

Title: Satisfaction with Care – A Measure of Quality of Care among Prostate Cancer Patients?

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ABSTRACT

Context: Patients' assessment of quality of care, outcomes and satisfaction with care has become a central issue in patient centered prostate cancer (PCa) care.

Objective: To analyze the association between patient-reported satisfaction with care and health related quality of life (HRQoL) and cost of care among newly diagnosed PCa patients.

Design: Prospective cohort study.

Setting, Patients and Main Outcome Measures(s): A total of 602 newly diagnosed PCa patients were recruited from an urban academic hospital and a VA hospital. All participants provided HIPAA and informed consent. Participants completed Satisfaction with care (CSQ-8) and HRQoL (SF-36, and UCLA-PCI) surveys prior to their treatment and at 3, 6, 12 and 24 months follow-up. Resource use and related costs were obtained through hospital based administrative databases. Correlation between return to baseline for HRQoL domains and satisfaction with care was measured at each follow-up using Spearman rho. Regression models were used to assess strength of association between HRQoL and total cost with satisfaction with care, after adjusting for socio-demographic and clinical covariates.

Results: General health had positive correlation with satisfaction with care at all follow-up points. At six months most of the domains for generic and prostate specific HRQoL had positive correlation with satisfaction with care. Regression results indicated that higher satisfaction associated with greater odds of functional recovery at 12 months for physical function, role physical, bodily pain, sexual function, bowel bother and with increased cost of care.

Conclusions: Higher satisfaction with care was associated with better functional recovery for some of the HRQoL domains and cost of care. Future research should examine the association of process of care and patient reported outcomes over time with satisfaction with care. Until then, the health care systems and providers need to be cautious in using satisfaction with care as a measure of quality of care.

INTRODUCTION

Patient satisfaction has emerged as an important component of patient reported outcomes and quality of medical care (1). However, lack of theoretical advances and a rigorous standardized approach to measurement of satisfaction of care has hindered its wide spread assessment and use in clinical and policy decision making processes. Is patient satisfaction with care associated with the process of care, post-treatment outcomes and the overall quality of care they receive? The research findings so far regarding this association have been conflicting for a number of reasons (2-10). Patient satisfaction may be confounded by disease factors (e.g., stage, severity, comorbidity), expectations and uncertainty about treatment outcomes. This fact makes it particularly difficult to draw generalizations from aggregate data and may require analysis focused on an individual disease. Prostate cancer (PCa) remains the most common cancer diagnosis among men and variation in quality of care outcomes indicate the importance of issues related to satisfaction with care (10). Thus, we present a model to conceptualize taxonomy of patient satisfaction with care, followed by longitudinal assessment of the association between satisfaction with care and quality of care outcomes.

A Conceptual Model of Satisfaction with Care

The concept of satisfaction with care is distinct from patient health, quality-of-life and quality-of-care (11-21). Many factors related to process and outcomes of care, such as patient level, social and environmental attributes, may affect overall satisfaction with care but generally are not considered to fall under the purview of physicians and health care systems. Physicians and clinical researchers usually are interested in satisfaction with care or the aspects of satisfaction with care that relate to patient health, treatment decision or outcomes. On the other hand, health care systems are interested in satisfaction with care related to process of care, quality of care, outcomes and health resource utilization. Thus, three

components of satisfaction with care are - satisfaction with process of care (health care delivery), satisfaction with treatment choice/decision and satisfaction with outcomes (11,20).

Description of the Model

As shown in Figure 1, satisfaction with medical care intervention may be associated with various factors such as its structure, process of care, quality of care, effectiveness in changing the outcome, side effects and social and environmental factors. Measures of satisfaction can be thought of as existing on a continuum of increasing structure, process, outcome and quality of care. At one end of the continuum is structure of health care system or environment; at the other are more complex and integrated measures such as outcomes and quality of care. Importantly, patient satisfaction with care can provide useful information about a patient's attitude toward health, providers and medical services/interventions (21, 22). Assessment of patient satisfaction becomes complicated when a patient has no immediate physical sensation he/she can associate with treatment effects, such as reduced HRQoL and functioning. Self reported satisfaction with care, health resource utilization and HRQoL increasingly are being used to measure quality of care. Given only the care they experienced, patients may not have the knowledge to form an educated conclusion on how satisfied they should be with their care. They only can answer questions concerning satisfaction on emotional factors and other characteristics of individual relevance. Thus, interrelationships among these outcomes measures are complex and remain to be fully explored. Our study objective was to measure and characterize satisfaction with care and HRQoL and cost outcomes longitudinally among a cohort of newly diagnosed PCa patients. We hypothesize that satisfaction with care is positively related to HRQoL and cost. Additionally, we explored the association of satisfaction with care with generic HRQoL, prostate-specific HRQoL and cost of care, adjusting for comorbidity, demographic and clinical characteristics.

METHODS

In this prospective cohort study, PCa patients were recruited from a large urban academic medical center and an academic VA medical center between 2002 and 2005. The study was approved by the local institutional review boards. All study personnel completed human subject protection training and met appropriate health information portability and accountability act education (HIPAA) requirements before engaging in this research. Study inclusion criteria were: self identified African American or Caucasian men of age = 45 yrs at the time of diagnosis, newly diagnosed for PCa in the prior four months and yet to initiate treatment. Diagnosis of PCa was based on prostate specific antigen (PSA) level, prostate biopsy and staging. Patients were excluded if they were diagnosed with metastatic cancer (10%), had visited the urology clinics for a second opinion only (18%), were unable to communicate in English (0%), and/or were cognitively impaired (< 1%).

Subject selection and recruitment

Recruitment: Eligible patients were identified and recruited from the two institutions' urology clinics. Potential participants received study information from their urologists during clinic visits or at the weekly prostatectomy classes. Study research assistant then contacted those who expressed interest and provided additional study and consent information. Enrolled patients provided written informed consent and HIPAA consent prior to any data collection.

Retention Plan and Follow-up: After providing baseline data, participants received follow-up surveys via mail at three, six, twelve and twenty-four months. Non-respondents were contacted via telephone after ten days and a second mailing was sent to them within four weeks of the first mailing. During study enrollment and scheduled clinic visits, the importance of active participation was emphasized.

Outcome Measures and Data Collection

Participants provided self-reported information on ethnicity, education, marital status, living arrangement and income. Structured medical chart review was used to collect data on patient age, date of PCa diagnosis, health insurance, treatment type, PSA score at diagnosis and at follow-up, Gleason score, TNM stage of cancer and comorbidity. Treatment for PCa was classified as radical prostatectomy (RP), external beam radiation therapy (EBRT), hormone therapy and watchful waiting.

To assess generic and prostate-specific HRQoL and satisfaction with care, participants completed self-administered surveys at enrollment (baseline) and at 3, 6, 12 and 24 months followup. Prostate-specific HRQoL was assessed using the UCLA Prostate Cancer Index (PCI), a comprehensive self-administered 20-item questionnaire that quantifies prostate-specific HRQoL in six domains of urinary function, urinary bother, sexual function, sexual bother, bowel function, and bowel bother (23). PCI has performed well in older population, has demonstrated good psychometric properties with internal consistency reliability ranging from 0.82-0.94, is well understood, and easy to complete (23). Generic HRQoL was measured using the Medical Outcome Study Short Form (SF-36), a single multi-item scale that assesses eight health concepts: physical limitation caused by health problems, limitations on social activities caused by physical/emotional problems, role limitations caused by physical health problems, and emotional problems, bodily pain, general mental health, vitality, and general health perceptions.(24) It was constructed for self-administration or administration by a trained interviewer, either in person or by telephone. It has exhibited high psychometric properties with internal consistency reliability ranging from 0.80-0.93 (24). Range of possible score for each of the eight sub-scales is 100%- 0%. Higher score on SF-36 or PCI indicates superior quality-of-life.

Satisfaction with care is defined as a pleasant feeling caused by the fulfillment of expectations (22) and was measured by the Client Satisfaction Questionnaire (CSQ-8), an eight-item, self-administered and easily scored measure. The items for the CSQ-8 are unidimensional and yield a

homogeneous estimate of general satisfaction with services. This questionnaire has been extensively studied and has demonstrated good psychometric properties with internal consistency reliability ranging from 0.86-0.94 (25). Possible scores for each sub-scale range from 1- 4 with a total score range of 8-32. A higher score on CSQ-8 indicates greater patient satisfaction with care. Baseline Charlson comorbidity index (26) was computed using ICD9 codes for all inpatient and outpatient events during three months prior to PCa diagnosis, obtained from hospital based administrative databases.

Data on health resource utilization, procedures and direct medical care charges for the non-VA patients were obtained from the Pennsylvania Integrated Clinical and Research Database (PICARD). This database integrates administrative, inpatient and outpatient information from the university practices and data from other clinical networks. We used cost-to-charge ratio of 0.60 to convert medical center charges to costs. Costs related to VA participants were obtained from the VHA services using Patient Treatment File (PTF or inpatient file) and the Outpatient Care Files (OPC). For each participant, outpatient events (visits, procedures and labs) and inpatient DRG and events are captured from the patient-specific clinical databases of Veterans Health Information Systems and Technology Architecture (VISTA) system, local electronic medical record (27). The data used for measuring direct medical care costs of PCa illness were: hospital care costs, physician and other professional caregivers' payments, medication costs, costs related to detection, costs of initial and follow-up treatments and treatment of complications. Costs per service were attributed to each service for every diagnosis for each study patient from actual charges for that patient. Data on type and number of services received by a patient, including those attributable to PCa, were obtained using CPT codes. Mean direct medical care cost per patient during the 24 months period was computed.

Statistical Analysis

Descriptive analysis of demographic and clinical variables was performed. Change of seven points or less on the generic and prostate-specific HRQoL, which is considered to be clinically significant difference, was defined as 'return to baseline' (23, 28). Spearman rho correlation was used to assess the

strength of association between percent returning to baseline and satisfaction with care total score over 3, 6, 12 and 24 months of follow-up. Logistic regression assessed the association between return to baseline at 12 month and satisfaction with care, after adjusting for demographic and clinical variables. A log-linear regression model analyzed the association between total cost of care and satisfaction with care. The following covariates were dichotomized: race (1: African American, 0: Caucasian); marital status (1: married, 0: other); education (1: high school or less, 0: = high school); treatment group (1: RP, 0: other); income (1: = \$40,000, 0: < \$40,000), employment (1: full-time, 0: other) and TNM stage (1: T1a to T2a, 0: T3a to T3b).

RESULTS

Table 1 displays the patient demographic and clinical characteristics. We recruited 602 newly diagnosed PCa patients with mean age of 63 yrs (SD=8.0). Of the 602 participants who completed baseline assessment, 487 completed three month follow-up assessment, 536 completed six month follow-up assessment, 512 completed twelve month and 502 completed 24 month follow-up assessment. The majority of the group was Caucasian (67%), college educated (65%), married (72%), employed part-time (63%) and had average income of 40,000 or more. The most widely reported symptom at baseline was to having to urinate too often (45%), followed by weak urinary stream. The average Charlson comorbidity score was 1.3 (SD=2.4), most frequent TMN stage was T1c and a majority of the patients received RP.

Baseline Satisfaction with Care and HRQoL:

Table 2 presents the baseline generic and prostate specific HRQoL scores, higher score indicating improved function. The group reported highest mean score for social function (82.7; SD= 24.1) and lowest mean score for sexual function (51.9; SD=30.1). The overall mean level of satisfaction was reported to be high (25.9; SD=5.2) with the majority of the patients reporting that they would recommend the “program” to a friend.

Longitudinal assessment of HRQoL, cost of care and satisfaction with care:

The longitudinal trend of association between satisfaction with care total score and percent returning to baseline is presented in Table 3. Spearman rho correlation coefficients showed that return to baseline for general health had positive and significant correlation with satisfaction with care at all follow-up points. At three months and at baseline (not reported), no significant association was noted between most of the HRQoL subscales and satisfaction with care. However, by six months, most of the domains for generic and prostate specific HRQoL had positive and significant correlation with satisfaction with care. This

trend continued at 12 month and at 24 month of follow-up. Results of logistic regressions for predicting association between return to baseline at 12 month (for generic and prostate-specific HRQoL subscales) and satisfaction with care total score are presented in Tables 4 and 5. Satisfaction with care total score was a significant predictor of return to baseline at 12 month for physical function, role physical and bodily pain. In all these cases, higher satisfaction was associated with greater odds of functional recovery (Table 4).

With respect to the prostate specific HRQoL, Table 5 indicates that satisfaction with care was associated with return to baseline for sexual function and bowel bother, higher satisfaction with care increased the odds of functional recovery for these two subscales. The last column in Table 5 presents the results of the log-linear regression that demonstrates a positive association between satisfaction with care and total cost.

DISCUSSIONS

Satisfaction with care is an important element of patient reported outcomes and plays a vital role in clinical assessment (19-21). As the population ages, burden of PCa on health care system will increase significantly. We assessed the longitudinal association between satisfaction with care and HRQoL and cost of care in newly diagnosed PCa patients. The main findings of this study are: (1) Higher satisfaction with care indicates better odds of functional recovery for some of the domains of generic (physical function, role physical and bodily pain) and prostate-specific (sexual function and bowel bother) HRQoL; (2) At six months follow-up, satisfaction with care was correlated with most of the generic and prostate specific HRQoL domains; (3) Satisfaction with care was associated with total cost of care; (4) Satisfaction with care was significantly associated with recovery for general health at all follow-up points; and (5) As depicted in the conceptual model, to be an effective quality of care measure, satisfaction with care must incorporate three components - satisfaction with process of care, satisfaction with treatment choice/decision and satisfaction with outcomes.

Many factors are associated with satisfaction with care such as patient characteristics, physician-patient interaction, process of care and outcomes (29-34). A study of mentally ill patients showed that quality-of-life was unrelated to satisfaction with services but was strongly associated with unmet needs related to mental and physical health and rehabilitation (2). Many studies have established a causal link between health and satisfaction with care (3,12,13,35). However, poor health may produce dissatisfaction directly as well as through the mediating effect of physicians' behavior in treating patients with poor health (3,12). Additional research is needed to understand the nature of relationship between health status and satisfaction with care.

In a cross sectional study, Johnson JA et al., concluded that satisfaction with care is more closely related to mental health status than to physical health status (13). In a study of 2365 men with clinically

localized PCa receiving an active treatment, believing oneself to be free of cancer, avoiding treatment complications, and having good overall health and social support were positively associated with satisfaction (6). However this study did not use a validated measure of satisfaction with care. Prostate cancer treatment may lead to complex outcomes and inadequate measure of such outcomes may bias the results. Aggressive treatment of PCa has been found to improve confidence in cancer control, yet be countered by diminished intimate relationships and masculinity that accompany sexual dysfunction (36). Since the dramatic nature of PCa can strongly alter satisfaction with care, patient-centered measures of the outcomes should include assessment of multiple domains (9). Persons with lesser illnesses may be less uncertain about their expected outcomes of medical intervention and so focus more on the aspect of their care that did not satisfy them. Improvement in patient reported clinical outcomes were shown to be associated with higher satisfaction with care (24). Also, process of care could be related to satisfaction with care (7). Hence, it is crucial for satisfaction with care to be inclusive of outcomes and process of care. Additionally, confidence in the medical system, having a regular source of care, and being satisfied with life in general are more important predictors of patient satisfaction than their demographic characteristics (33).

Patients often have trouble evaluating their quality of care, especially when many variables are included in its determination (14-21,37). As patients often do not have an extensive medical background, they may ignore harder to evaluate characteristics of their treatment, instead focusing on those aspects they readily understand regardless of merit. Though satisfaction with care can be a consequence and a determinant of health status, the effects of health status on satisfaction may be more important than the effects of satisfaction on health status (20,21,35). There exists significant variation between measurements of satisfaction with care using single item question and those obtained using validated survey instruments, and conclusions derived (14,15). Evaluation of satisfaction with care

depends on the method used. Unreliability of measurement may be a significant problem in satisfaction with care assessment and its effectiveness as a quality of care measure (14-44). Specifically where satisfaction of care is concerned, hypothetically, a patient may be equally satisfied with quality or perfunctory care regardless of the treatment type since the patient may not have enough medical knowledge to determine whether he/she should be dissatisfied. On the other hand, one can argue that patients possess a good idea of what constitutes sound process for the treatment of many or the more common medical problems. Patients do experience, perhaps better than anyone else, the health status outcomes of their care. Because these outcomes probably are weakly related to the quality of medical care process, they provide few clues about medical care quality (44-46). Treatment satisfaction includes a rather broad range of aspects including quality of care, patient characteristics, physician-patient interaction/communication, process of care, and environmental factors that go beyond the specific treatment or therapy (4,21-47). Thus, in the era of comparative effectiveness of health care interventions, satisfaction with care can play an important role in assessment of quality of care (19-21).

Other studies also show that patient's assessment of the quality of their care does not seem to be directly related to objective measures of care quality (48-49). In an Italian study involving 825 female breast cancer patients, the majority of the women made favorable judgments about their care providers and were moderately or highly satisfied with the care rendered; nevertheless, objective markers showed that the quality of some of the information the patients had received was sub-par with respect to predefined criteria (5). This is noteworthy in light of Larson's study which found patient satisfaction to correlate to having their informational needs met; however, not all information about a patient's condition leads to increased satisfaction with care (2). Additionally, Hall's study found that in some cases, poor health causes dissatisfaction with care directly or as a result of the mediating effect of the patient's physician's behavior (3). Lantz PM, et al, (2005) using a cross section study reported

satisfaction with the both process and the outcomes. However, patients' involvement in the decision process not necessarily lead to increased satisfaction with care (43). Another important domain, health insurance status was also shown to have significant affect on satisfaction with care. Burton LC et al., reported that patients enrolled in a managed care organization were more likely to be highly satisfied in three domains of global quality, access to care, and technical skills-compared with patients in the local and national fee-for service study groups (47).

This study has several strengths and limitations. To our knowledge, this is the first study reporting longitudinal assessment of satisfaction with care and its association with other outcomes (HRQoL and cost) for newly diagnosed PCa patients. This study tackles important and intriguing area of patient reported outcome measures that have received little attention and adds to the extant literature in many ways. The conceptual model developed here can aid effective application of satisfaction with care in outcomes research and evaluation. Disease specific and longitudinal assessment of satisfaction with care helps us to analyze its association with other outcomes and provide more robust conclusions. However, despite these and other strengths, there are certain limitations. The generalizability of the findings may be limited because the population observed was from a large urban academic hospital and a VA hospital. Causal inferences are restricted due to the non-experimental study design. Finally, the direction of causation can be reverse to one that we have assumed.

Conclusion: Satisfaction with care was associated with some domains of generic and prostate specific HRQoL. However, the wide variation in measurement of satisfaction with care is a major hurdle in its effective application in policy and clinical outcome studies. In this era of value based care and where any decision in the health care setting may have implications in terms of risks, benefits and costs, valid assessment of satisfaction with care can play an important role. Thus, refined tools are desired to measure disease specific and generic measures of satisfaction with care based on process and outcomes

(20). Lack of gold standard in measuring satisfaction with care provides significant opportunity to not only to standardize the measurement of satisfaction with care (based on conceptualization model) but also development of valid instruments (generic and disease specific). Satisfaction with care is a fertile ground in health services research that remains to be cultivated and harvested.

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Figure 1: Conceptual Model of Measures of Satisfaction with Care

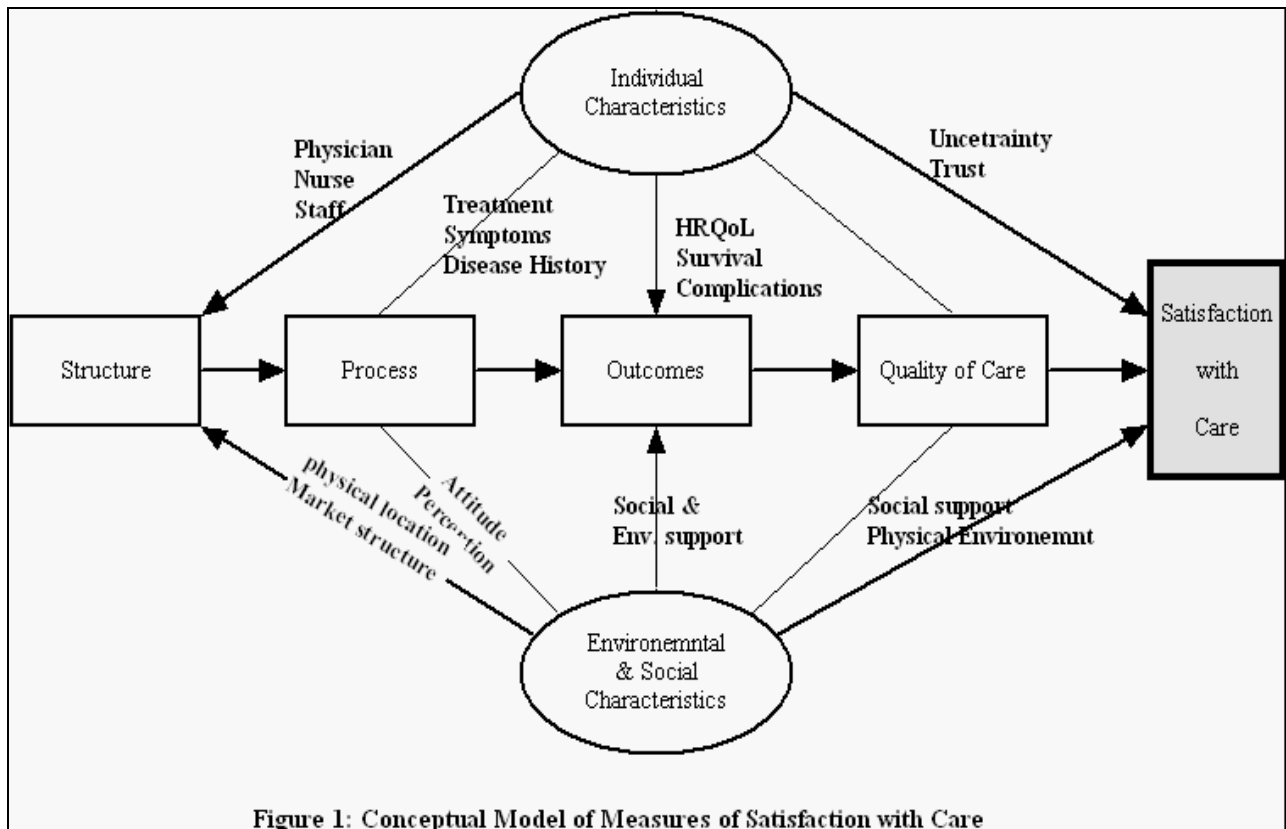


Table 1: Demographics and clinical characteristics of the study sample (n=602)

| Covariates | | |
|--|-----|-----------|
| <u>Age (mean ± std)</u> | | 6.3 (8.0) |
| <u>Charlson comorbidity (mean ± std)</u> | | 1.3 (2.4) |
| <u>Race (%)</u> | | |
| African American | | 32.26 |
| Caucasian | | 67.74 |
| <u>Education (%)</u> | | |
| College or more | | 64.80 |
| HS or less | | 35.20 |
| <u>Marital Status (%)</u> | | |
| Single/Widowed/Div | | 27.47 |
| Married | | 72.53 |
| <u>Employment Status (%)</u> | | |
| Part-time/other | | 61.99 |
| Full-time | | 38.01 |
| <u>Income Level (%)</u> | | |
| > \$40,000 | | 60.30 |
| ≤ \$40,000 | | 39.70 |
| <u>Signs and symptoms (%)</u> | | |
| Difficulty or discomfort urinating | | 21.62 |
| Having to urinate too often | | 45.53 |
| Weak urinary stream | | 34.76 |
| Infection of bladder or prostate | | 8.42 |
| Blood in urine | | 7.55 |
| Pain or aches in back, hips or legs | | 29.8 |
| More tired or worn out than usual | | 25.36 |
| PSA-at diagnosis (ng/ml) (mean ± std.) | | 7.6 (8.0) |
| Gleason score (total) (mean± std.) | | 6.3 (0.9) |
| TNM stage (%) | T1a | 1.84 |
| | T1b | 3.61 |
| | T1c | 62.87 |
| | T2a | 15.08 |
| | T2b | 2.57 |
| | T2c | 3.31 |
| | T3a | 7.35 |
| | T3b | 3.31 |
| Treatment Type: (%) | | |
| Radical Prostatectomy | | 61.70 |
| External Beam Radiation Therapy | | 32.30 |
| Hormonal Therapy | | 12.09 |
| Watchful waiting | | 2.27 |

Table 2: Baseline Health Related Quality of Life and Satisfaction with Care

| Variable | Mean (SD) |
|--|-------------|
| <u>RAND 36 item Generic HRQoL</u> | |
| Physical function | 62.7 (21.8) |
| Role physical | 74.7 (39.1) |
| Role emotional | 76.8 (37.9) |
| Vitality | 65.1 (22.7) |
| Mental health | 76.5 (18.2) |
| Social function | 82.7 (24.1) |
| Bodily pain | 81.8 (24.4) |
| General health | 67.4 (22.7) |
| <u>UCLA prostate cancer specific HRQoL</u> | |
| Urinary function | 89.2 (18.6) |
| Bowel function | 87.6 (14.8) |
| Sexual function | 51.9 (30.1) |
| Urinary bother | 85.3 (23.4) |
| Bowel bother | 88.7 (21.3) |
| Sexual bother | 61.3 (38.6) |
| <u>Satisfaction with care</u> | 25.9 (5.2) |

Table 3: Correlation between Return to Baseline and Satisfaction with Care

| Return to baseline | Satisfaction with Care-total Score | | | | | | | |
|--------------------|------------------------------------|---------|---------|---------|----------|---------|----------|---------|
| | 3 month | | 6 month | | 12 month | | 24 month | |
| | Corr. | P value | Corr | P value | Corr | P value | Corr | P value |
| Physical function | -0.0013 | .9970 | .1456 | .0043 | .0984 | .0529 | .0416 | .4949 |
| Role physical | -0.0298 | .6711 | .1433 | .0055 | .1466 | .0042 | .09156 | .1204 |
| Role emotional | 0.0165 | .7525 | .10327 | .0463 | .1057 | .0400 | .10556 | .0842 |
| Vitality | 0.0670 | .2045 | .07921 | .1237 | .0816 | .1078 | .04574 | .4322 |
| Mental health | 0.0940 | .0863 | .0574 | .2647 | .1415 | .0037 | .15051 | .0093 |
| Social function | 0.0865 | .0958 | .1527 | .0029 | .1509 | .0028 | .17675 | .0022 |
| Bodily pain | -0.005 | .9243 | .1509 | .0032 | .1355 | .0076 | .15980 | .0059 |
| General health | 0.2123 | <.0001 | .1933 | <.0001 | .1691 | .0008 | .10970 | .0057 |
| Urinary function | -0.0851 | .1015 | -.0091 | .8592 | .1361 | .0074 | .14440 | .0137 |
| Bowel function | 0.0970 | .0864 | .1428 | .0054 | .1808 | .0004 | .21145 | .0003 |
| Sexual function | -0.0372 | .4816 | -.0220 | .6712 | .00715 | .8902 | .13459 | .0231 |
| Urinary bother | -0.0299 | .5669 | -.0116 | .7701 | .10516 | .0394 | .24024 | <.0001 |
| Bowel bother | 0.0349 | .5029 | .09931 | .0540 | .12670 | .0130 | .26779 | <.0001 |
| Sexual bother | -0.0982 | .094 | -.0614 | .2481 | -.0039 | .9490 | .18832 | .0016 |

Table 4: Satisfaction with care and Return to baseline values for Generic HRQoL scales

| RAND 36 Item health Survey | | | | | | | | |
|----------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Independent variables | Physical function | Role physical | Role emotional | Vitality | Mental health | Social function | Bodily pain | General health |
| | OR (SE) | OR (SE) | OR (SE) | OR (SE) | OR (SE) | OR (SE) | OR(SE) | OR (SE) |
| Age at treatment | 0.958 (0.03) | 0.982 (0.03) | 0.982 (0.94) | 1.002 (0.03) | 1.027 (0.03) | 1.022 (0.02) | 1.025 (0.02) | 1.043 (0.03) |
| AA-Ethnicity | 0.312 * (0.51) | 0.664 (0.52) | 0.864 (0.65) | 1.854 (0.48) | 1.659 (0.56) | 1.258 (0.48) | 0.457 (0.43) | 0.772 (0.46) |
| Charlson Comorbidity | 0.995 (0.09) | 0.956 (0.08) | 0.999 (0.12) | 0.908 (0.07) | 0.927 (0.09) | 0.949 (0.08) | 0.979 (0.07) | 1.106 (0.09) |
| PSA at baseline | 1.048 (0.04) | 0.988 (0.02) | 1.020 (0.04) | 1.015 (0.02) | 1.130 * (0.06) | 0.995 (0.02) | 0.996 (0.02) | 0.977 (0.02) |
| TNM stage | 1.160 (0.18) | 0.505 (0.93) | 0.265 (0.12) | 2.056 (0.94) | 999 (377) | 0.834 (0.93) | 2.575 (1.12) | 0.452 (0.87) |
| Gleason score | 0.657 (0.25) | 0.892 (0.23) | 1.218 (0.31) | 0.763 (0.21) | 0.702 (0.25) | 1.102 (0.21) | 0.926 (0.19) | 0.983 (0.20) |
| Education | 0.617 (0.48) | 1.616 (0.50) | 0.508 (0.60) | 1.102 (0.39) | 0.429 (0.46) | 0.561 (0.41) | 1.755 (0.40) | 1.269 (0.41) |
| Married | 1.754 (0.53) | 0.975 (0.54) | 8.103 * (0.63) | 1.395 (0.46) | 1.852 (0.53) | 1.516 (0.47) | 0.926 (0.46) | 0.978 (0.47) |
| RP-Treatment | 1.125 (0.55) | 1.638 (0.51) | 1.985 (0.67) | 2.353 * (0.42) | 1.908 (0.52) | 0.276 (0.47) | 2.665 * (0.42) | 2.510 * (0.43) |
| Satisfaction with care | 1.112 * (0.03) | 1.080 * (0.03) | 1.011 (0.05) | 1.051 (0.03) | 1.057 (0.04) | 1.049 (0.03) | 1.069 * (0.03) | 1.085 * (0.03) |
| Non-VA hospital | 1.502 (0.59) | 1.623 (0.59) | 1.676 (0.69) | 2.744 * (0.50) | 2.012 (0.59) | 2.834 * (0.53) | 0.608 (0.51) | 1.022 (0.52) |
| R ² | .3637 | .2294 | .4213 | .2713 | .2852 | .2592 | .2327 | .2237 |

RP= Radical Prostatectomy; AA=African American; PSA=prostate specific antigen

* p <.05

Table 5: Satisfaction with care and Return to baseline for Prostate Specific HRQoL scales

| UCLA-Prostate Cancer Index | | | | | | | |
|----------------------------|---------------------|-------------------|--------------------|-------------------|-------------------|-------------------|---------------------|
| | Urinary function | Bowel function | Sexual function | Urinary bother | Bowel bother | Sexual bother | Total Cost (log) |
| | OR (SE) | OR(SE) | OR (SE) | OR (SE) | OR (SE) | OR (SE) | OR (SE) |
| Intercept | | | | | | | 1032 (1.3) |
| Age at treatment | 1.024 (0.02) | 1.001 (0.03) | 1.075 * (0.03) | 1.036 (0.02) | 1.021 (0.03) | 1.063 * (0.03) | 1.03* (0.01) |
| AA-Ethnicity | 0.937 (0.43) | 1.163 (0.49) | 0.553 (0.59) | 0.540 (0.41) | 0.79 (0.51) | 0.795 (0.44) | 1.4 (0.25) |
| Charlson Comorbidity | 1.082 (0.07) | 0.914 (0.08) | 1.240 * (0.09) | 0.947 (0.07) | 1.02 (0.09) | 1.150 (0.07) | 1.07 (0.04) |
| PSA at baseline | 1.064 (0.04) | 0.982 (0.02) | 0.998 (0.02) | 1.054 (0.03) | 1.05 (0.03) | 1.07 (0.02) | 0.99 (0.03) |
| TNM stage | 0.263 (1.00) | 1.469 (1.18) | 0.316 (1.18) | 0.349 (0.90) | 0.69 (0.04) | 0.97 (1.02) | 1.41 (0.51) |
| Gleason score | 1.022 (0.19) | 1.144 (0.22) | 0.726 (0.25) | 1.197 (0.19) | 0.96 (0.21) | 0.92 (0.20) | 1.10 (0.13) |
| Education | 1.078 (0.38) | 1.390 (0.46) | 0.488 (0.51) | 0.794 (0.37) | 0.90 (0.47) | 0.56 (0.40) | 1.52* (0.21) |
| Married | 1.693 (0.46) | 2.072 (0.49) | 1.471 (0.62) | 1.266 (0.44) | 2.02 (0.49) | 2.17 (0.49) | 1.34 (0.25) |
| RP-Treatment | 0.259 * (0.44) | 1.951 (0.47) | 0.222 * (0.49) | 0.895 (0.42) | 3.45 * (0.49) | 0.64 (0.43) | 0.92 (0.26) |
| Satisfaction with care | 1.047 (0.03) | 1.091 * (0.03) | 1.135 * (0.05) | 1.055 (0.03) | 1.108 * (0.03) | 0.964 (0.03) | 1.12* (0.02) |
| Non-VA hospital | 1.463 (0.51) | 1.129 (0.55) | 0.664 (0.67) | 0.936 (0.49) | 1.936 (0.55) | 1.255 (0.53) | 1.32 (0.29) |
| R ² | .2827 | .2544 | .4121 | .2057 | .3573 | .2479 | .2375 |

RP= Radical Prostatectomy; AA=African American; PSA=prostate specific antigen

* p <.05

Title: Assessment of Indirect Costs of Newly Diagnosed Prostate Cancer Patients

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Title: Assessment of Indirect Costs of Newly Diagnosed Prostate Cancer Patients

a. Introduction and Objective: Assessment of indirect cost (IC) plays an important role in prostate cancer (PCa) outcome research and management. We compared self-reported IC of newly diagnosed PCa patients receiving either radical prostatectomy (RP) or external beam radiation therapy (EBRT).

b. Methods: We developed a two part survey to assess self-reported IC. First part consisted of six items related to non-medical care expenses of PCa treatment. Second part assessed patient and caregiver(s) time. Prospective cohort design was used to recruit 495 newly diagnosed PCa patients from urology clinics of an urban academic hospital and a VA hospital. All participants provided HIPAA and informed consent. Participants completed demographic and self reported IC surveys prior to treatment and at 3, 6, 12 and 24 months follow-up. Clinical data were obtained via medical chart review. Parametric and non-parametric tests were used to compare demographic and clinical attributes and indirect costs across RP and EBRT groups. Multivariate regression models were used to assess factors associated with total IC.

c. Results: Compared to EBRT, RP group was younger (59.3 vs. 66.3, $p<.0001$), mostly Caucasian ($p=.002$), married ($p<.0001$) and worked full time ($p<.0001$). Gleason score and TNM stage were comparable between groups. The RP group had lower PSA score at diagnosis ($p=.002$) and lower Charlson comorbidity ($p=.003$). At six and 12 month of follow-up, fewer participants from RP group reported out of pocket expenses, whereas, this number increased significantly for EBRT group. Mean out of pocket expenses for medications over 12 month period was significantly lower ($p=.05$) for RP group (\$98.4, SD=\$112) vs. that for EBRT group (\$112, SD=609). At 3 months, higher percent of EBRT group needed more time to travel than RP group ($p=.05$). The trend continued at 12 month ($p=.0007$). At three months, higher

proportion of RP group had missed/reduced work ($p=.004$), trend continued at six month ($p=.05$), though not at 12 month. At three and six months, higher percent of EBRT group reported taking more time to do usual housework ($p=.0002$) and needed more help from caregivers ($p=.05$) by six months. Log linear regression indicated that RP was associated with lower medication expenses ($PE=0.79$, $p=0.01$), after adjusting for age, Charlson comorbidity, race and TNM stage.

d. Conclusions: This novel study to assess indirect cost between two curative treatments for PCa showed significant variation in indirect costs across time and treatment. Total indirect cost related to medication was lower for RP group.



Hospital Ownership and Quality of Prostate Cancer Care

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Abstract

(a) Introduction and Objective: Hospital ownership has an impact on quality of care and outcome for prostate cancer (PCa). We analyzed the variation in treatment and patient reported outcomes of newly diagnosed PCa patients from VA and non-VA hospitals.

(b) Methods: Prospective cohort design was used to recruit 487 newly diagnosed PCa patients (VA=174; non-VA=313) between 2003-2005. All participants provided HIPAA, informed consent, and completed following surveys (at baseline and at 3, 6, 12 and 24 months): Client Satisfaction with Care (CSQ-8), Quality of Wellbeing (QWB-SA) generic (SF-36) and PCa specific (UCLA-PCI) HRQoL. Clinical data were obtained via medical charts. T-test, chi-sq and ANOVA were used to compare demographics, quality of wellbeing and HRQoL. Survival analysis was used to compare time to return to baseline across VA and non-VA hospitals. Multivariate analyses were used to study the association of hospital ownership with post treatment HRQoL.

(c) Results: Demographic attributes varied between groups. VA group was older (mean age = 65.35 vs. 60.81; $p = <.0001$). Non-VA group was mostly Caucasian ($p < .0001$), higher income, higher education, more likely to work fulltime and married. At baseline, mean QWB-SA was comparable between groups (0.72 vs. 0.67; $p = 0.10$). At 12 months, VA group had lower QWB-SA ($p = 0.03$). VA group had significantly lower generic and PCa-specific HRQoL at baseline and the trend continued over time. TNM stage and Gleason score at diagnosis were comparable. Mean PSA at diagnosis (10.6 vs. 6.7, $p = <.0001$) and mean Charlson comorbidity (1.90 vs. 1.18; $p = .02$) were higher for VA group. Treatment varied significantly by hospital group. Higher proportion of VA group had radiation (72.73%) compared to non-VA group (20.3%). Log linear regression showed that at 12 month, non-VA hospital status was associated with higher generic (physical function-OR = 1.4, $p = .02$; role physical-OR = 3.1, $p = .0001$; emotional function-OR = 2.2, $p = .007$; vitality-OR = 1.2, $p = .04$; mental health-OR = 1.1, $p = .04$; social function-OR = 1.4, $p = .0001$; bodily pain-OR = 1.4, $p = <.0001$; and general health-OR = 1.3, $p = .007$) and prostate specific HRQoL scores (urinary function-OR = 1.4, $p = <.0001$, bowel function-OR = 1.2, $p = .0001$; sexual function-OR = 1.7, $p = .05$; urinary bother-OR = 1.9, $p = .0008$; and bowel bother-OR = 1.4, $p = .006$) after adjusting for demographic and clinical factors.

(d) Conclusions: Hospital ownership is associated with variation in treatment, quality of care and outcome. The differences in patient mix must be considered while addressing disparity in PCa outcomes. The results demand further research on hospital ownership, process of care and their effects on PCa care.

Background

- Prostate Cancer is the leading cancer diagnosis in men with an estimated 234,460 new cases in 2006.
- Probability of developing prostate cancer increases with age. 70% of these cases are expected to be older than 65, with mean age at diagnosis of 70 years.
- African American men (274 per 100,000) are 1.6 times more likely to be diagnosed with prostate cancer than White men (171 per 100,000).
- Although the mortality rates (30,350 deaths in 2005) are declining, the rates are still disproportionately higher (2.5 times) in African American men.
- Earlier research has shown wide variation in quality of prostate cancer care across age, ethnicity, region and hospitals.
- Hospital characteristics play an important role in the variation in quality of prostate cancer care.

Objectives

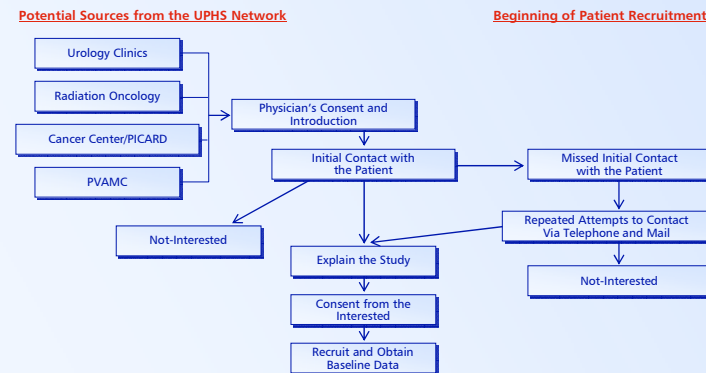
- To compare self-reported satisfaction with care and health related quality of life of newly diagnosed prostate cancer patients between VA and non-VA hospitals.
- To study predictors of health related quality of life and satisfaction with care for prostate cancer, controlling for treatment, ethnicity, disease stage at diagnosis and comorbidity.

Methods

- Prospective cohort design
- Age ≥ 45 years
- Study participants: African American and Caucasian men diagnosed for prostate cancer
- Patients are recruited within four months of their diagnosis and prior to treatment
- Patients are recruited from: non-VA and VA hospitals
- Sample size \Rightarrow 487 patients
- Quality of life \Rightarrow UCLA Prostate Cancer Index (PCI), SF-36, and FACT-p
- Quality of well-being-QWB-SA
- Satisfaction with care \Rightarrow CSQ-8
- Health resource utilization and direct medical care cost \Rightarrow PICARD and for VA patients through unit cost approach
- Clinical data \Rightarrow Medical chart review
- HRQoL and Satisfaction with care data was obtained at baseline, 3, 6, 12 and 24 months

Process of Recruiting & Retention

Recruitment Strategy for Prostate Cancer Patients



Analysis

- T-test, Chi-sq and ANOVA were used to compare demographics, QWB and HRQoL.
- Multivariate log-linear analyses were used to study the association of hospital type with post treatment HRQoL.
- Survival analysis was used to compare time to return to baseline HRQoL.

Table 1. Comparison of Baseline Characteristics, Signs and Symptoms

| Covariates | Non-VA (n=313) | VA (n=174) | p value |
|-------------------------------------|----------------|------------|---------|
| Age (In years) | 60.8 (7.4) | 65.4 (8.1) | <.0001 |
| Charlson comorbidity | 1.18 (2.4) | 1.90 (2.3) | .0249 |
| Ethnicity/Race | | | |
| Caucasian | 83.07 | 40.80 | <.0001 |
| African American | 16.93 | 59.20 | |
| Marital Status | | | |
| Single/Widow/Div | 14.65 | 52.07 | <.0001 |
| Married | 85.35 | 47.93 | |
| Signs & Symptoms (%) | | | |
| Difficulty or discomfort urinating | 16.61 | 30.99 | .0002 |
| Having to urinate too often | 38.71 | 58.82 | <.0001 |
| Weak urinary stream | 32.59 | 38.79 | .1759 |
| Infection of bladder or prostate | 5.47 | 13.33 | .0029 |
| Blood in urine | 4.52 | 13.02 | .0007 |
| Pain or aches in back, hips or legs | 18.59 | 50.00 | <.0001 |
| More tired or worn out than usual | 14.94 | 44.58 | <.0001 |

Table 2. Clinical Characteristics at Baseline Across Hospital Type

| Clinical Characteristics | Non-VA (n=313) | VA (n=174) | p value |
|--------------------------|----------------|-------------|---------|
| PSA at diagnosis (ng/ml) | 6.7 (4.6) | 10.6 (15.3) | .0015 |
| Gleason score (total) | 6.3 (0.62) | 6.1 (1.45) | .1350 |
| TNM Stage (%) | | | |
| T1a | 2.33 | 0.00 | .3440 |
| T1b | 4.66 | 0.00 | |
| T1c | 63.73 | 56.60 | |
| T2a | 12.57 | 26.42 | |
| T2b | 2.33 | 3.77 | |
| T2c | 2.79 | 5.66 | |
| T3a | 8.85 | 1.89 | |
| T3b | 2.34 | 5.66 | |

Table 3. Comparison of Baseline HRQoL by Hospital Type

| HRQoL | Non-VA (n=313) | VA (n=174) | p value |
|---------------------------|----------------|-------------|---------|
| Generic HRQoL-SF36 | | | |
| Physical function | 70.7 (14.9) | 48.7 (24.7) | <.0001 |
| Role physical | 85.9 (30.3) | 54.8 (44.6) | <.0001 |
| Role emotional | 81.9 (34.6) | 66.5 (42.3) | <.0001 |
| Vitality | 70.4 (20.5) | 55.9 (23.6) | <.0001 |
| Mental health | 78.8 (16.9) | 72.1 (19.8) | <.0001 |
| Social function | 87.8 (19.7) | 73.5 (28.2) | <.0001 |
| Bodily pain | 88.6 (18.8) | 69.8 (28.3) | <.0001 |
| General health | 73.9 (19.9) | 56.3 (22.7) | <.0001 |
| PCa Specific | | | |
| Urinary function | 91.6 (17.4) | 84.8 (20.1) | .0001 |
| Bowel function | 90.6 (11.6) | 82.2 (18.0) | <.0001 |
| Sexual function | 58.6 (28.4) | 39.9 (29.5) | <.0001 |
| Urinary bother | 88.5 (20.8) | 79.4 (26.4) | .0001 |
| Bowel bother | 92.1 (16.8) | 82.9 (26.1) | <.0001 |
| Sexual bother | 65.5 (37.8) | 54.6 (38.9) | .0033 |

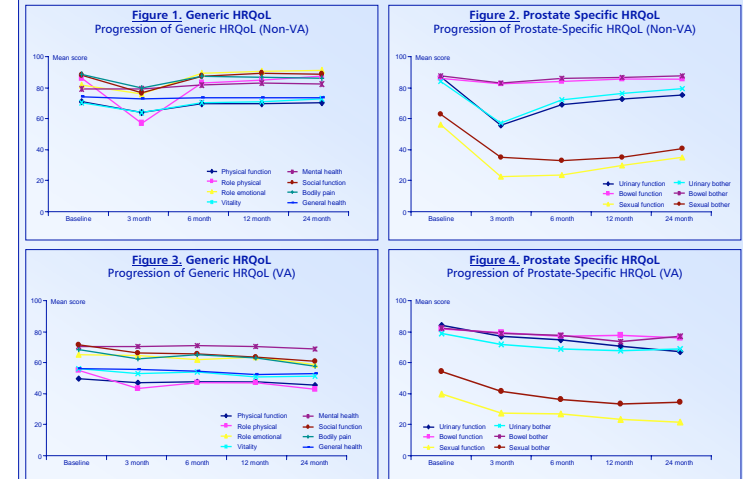
Table 4. Satisfaction with Care (CSQ-8)

| Satisfaction with Care Sub-Scales | Non-VA (n=236) | VA (n=140) | p value |
|--|----------------|------------|---------|
| How would you rate the service you have received? | | | |
| Poor/Fair | 7.86 | 2.53 | .0161 |
| Good/Excellent | 92.14 | 97.47 | |
| Did you get the kind of service you wanted? | | | |
| No | 3.80 | 7.80 | .0926 |
| Yes | 96.20 | 92.20 | |
| To what extent has treatment met your needs? | | | |
| None/Only a few | 4.70 | 15.83 | .0003 |
| Most/Almost all | 95.30 | 84.17 | |
| If a friend were in need of similar help, would you recommend our program to him? | | | |
| No | 1.73 | 5.63 | .0381 |
| Yes | 98.27 | 94.37 | |
| How satisfied are you with the treatment you have received? | | | |
| Dissatisfied | 5.96 | 9.22 | .2355 |
| Satisfied | 94.04 | 90.78 | |
| Have the services you received helped you to deal more effectively with your problems? | | | |
| No | 3.42 | 9.29 | .0171 |
| Yes | 96.58 | 90.71 | |
| In an overall sense, how satisfied are you with the service you have received? | | | |
| Dissatisfied | 5.11 | 9.93 | .6743 |
| Satisfied | 94.89 | 90.07 | |
| If you were to seek help again, would you come back to our program? | | | |
| No | 2.97 | 7.14 | .0595 |
| Yes | 97.03 | 92.86 | |

Table 5. Mean Days to Return to Baseline

| HRQoL | Non-VA (n=313) | VA (n=174) | p value |
|---------------------------|----------------|------------|---------|
| Generic HRQoL-SF36 | | | |
| Physical function | 170 | 175 | .0800 |
| Role physical | 180 | 166 | .9794 |
| Role emotional | 148 | 153 | .1479 |
| Vitality | 186 | 178 | .9390 |
| Mental health | 152 | 166 | .0363 |
| Social function | 183 | 202 | .0015 |
| Bodily pain | 185 | 205 | .0060 |
| General health | 159 | 177 | .0104 |
| PCa Specific | | | |
| Urinary function | 252 | 180 | <.0001 |
| Bowel function | 162 | 179 | .0625 |
| Sexual function | 297 | 220 | <.0001 |
| Urinary bother | 227 | 184 | .0033 |
| Bowel bother | 148 | 165 | .0103 |
| Sexual bother | 242 | 199 | .0010 |

Figures 1-4



Log Linear Regression Model

12 Month Non-VA Status Was Associated with Higher Generic and Prostate-Specific HRQoL:

- Physical function-OR=1.4, $p = .02$
- Role physical-OR=3.1, $p = .0001$
- Emotional function-OR=2.2, $p = .007$
- Vitality-OR=1.2, $p = .04$
- Mental health-OR=1.1, $p = .04$
- Bodily pain-OR=1.4, $p = <.0001$
- Social function-OR=1.4, $p = .0001$
- General health-OR=1.3, $p = .007$
- Urinary function-OR=1.4, $p = <.0001$
- Bowel function-OR=1.2, $p = .0001$
- Sexual function-OR=1.7, $p = .05$
- Urinary bother-OR=1.9, $p = .0008$
- Bowel bother-OR=1.4, $p = .006$

Quality of Wellbeing (QWB-SA)

- At baseline mean QWB-SA was comparable between groups (0.72 vs. 0.67; $p = 0.10$)
- At 12 months, VA group had lower QWB-SA ($p = 0.03$)

Conclusions

- Hospital ownership was associated with variation in treatment, quality of care and outcome.
- The differences in patient mix must be considered while addressing disparity in quality of prostate cancer care and outcomes.
- The results demand further research on hospital ownership, process of care and their effects on prostate cancer care.

